Atty. Docket No.: ISA-051.01

### Remarks

Claims 26, 35, 36, 44-50 and 55 are pending in the application. The Office Action states that the pending claims are free of the prior art (see paragraph 7).

For the reasons set forth below, Applicants submit that the pending claims, as amended, are in compliance with the enablement requirement of 35 USC § 112, first paragraph and are definite as required by 35 USC § 112, second paragraph.

### Claim Rejections

# 35 USC § 112, First Paragraph

Claims 55, 22-24, 29-30, 35-39 and 44-47 have been rejected under 35 USC § 112, first paragraph,

the specification, while being enabling for the detection of different isoforms of FSH and gonadotrophin and relating their relative abundance to the menopausal state of a human female, does not reasonably provide enablement for the detection of any and all other analytes and relating their relative abundance to the menopausal status of a human female.

Independent claim 55, from which all of the remaining claims depend, has been amended to require that the analyte compound be a member of the gonadotrophin family. As amended, the claims obviate this ground of rejection.

## 35 USC § 112, Second Paragraph

Claim 55 and 22-50 have been rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner contends that "[C]laim 55 is vague and indefinite because it appears to claim that any compound obtained from a human female and detected using the claimed method can be used to determine menopausal status."

Atty. Docket No.: ISA-051.01

As pointed out above, independent claim 55, from which all of the remaining claims depend, has been amended to require that the analyte compound be a member of the gonadotrophin family, thereby obviating this ground of rejection.

The Examiner further contends that Claim 55 is "vague because it does not make clear the amount of analyte detected with the specific menopausal status." In particular, the Examiner states that "[T]he determining step in part (f) is vague."

Independent claim 55, from which all of the remaining claims depend, has been further amended to clarify that the amounts determined in step (e) be displayed as a ratio; and to require in step (f) that the ratio in step (e) be compared to the ratio obtained from a pre-menopausal control, wherein a difference in the two ratios indicates that the human female is in a post-menopausal state. Therefore claims 55 and 22-50 are believed to be patentable.

Atty. Docket No.: ISA-051.01

### Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted, Patent Group Foley Hoag LLP

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